

## PIN10

## EFFECTS OF PILL BURDEN ON DISCONTINUATION OF THE INITIAL HAART REGIMEN IN MINORITY FEMALE PATIENTS PRESCRIBED 1 PILL/DAY VERSUS ANY OTHER REGIMEN

Hill S<sup>1</sup>, Kavookjian J<sup>1</sup>, Qian J<sup>1</sup>, Chung A<sup>2</sup>, Vande Waa JA<sup>3</sup><sup>1</sup>Auburn University, Auburn, AL, USA, <sup>2</sup>Auburn University, Mobile, AL, USA, <sup>3</sup>University of South Alabama, Mobile, AL, USA

**OBJECTIVES:** Highly active antiretroviral therapy (HAART) is a mainstay of treatment for patients with Human Immunodeficiency Virus (HIV). Given that lower HAART pill burdens have been shown to be associated with an increased duration of initial therapy, there is a need to understand the effect of daily pill burden on the duration of the initial regimen. The objective of this study was to estimate the effects of daily pill burden on the time to discontinuation of the initial HAART regimen. **METHODS:** A retrospective cohort design was used where adult, female, HIV-positive patients initiating therapy at the study clinic were included. A Kaplan-Meier curve was generated and a Cox proportional hazards model was developed to assess the impact of patient, regimen, and demographic characteristics on the hazard of discontinuation of the initial regimen. **RESULTS:** A total of 498 charts were reviewed, yielding a cohort of 115 adult female patients who initiated HAART at the study clinic. All study subjects were followed up from the initiation of HAART to treatment discontinuation. Patients treated with a 1 pill/day regimen had a significantly longer time to discontinuation than regimens of 2+ pills/day (mean duration of initial therapy 1574.97 days vs. 977.48 days, respectively,  $p=0.003$ ). Compared to 1 pill/day regimens, 2+ pills/day regimens were associated with a higher hazard of discontinuation (hazard ratio (HR) =3.44 with 95% confidence interval (CI) = 1.25, 9.48). Higher viral load and patients without insurance were also found to be significantly associated with higher hazards of discontinuation. **CONCLUSIONS:** The 1 pill/day regimen in the initial HAART treatment was associated with a lower hazard of discontinuation than any other regimen used.

## PIN11

## TRENDS IN GENOTYPIC RESISTANCE TESTING USE AND RESULTS AMONG ANTIRETROVIRAL-NAIVE PATIENTS IN THE HIV OUTPATIENT STUDY (HOPS)

Buchacz K<sup>1</sup>, Young B<sup>2</sup>, Palella FJ<sup>3</sup>, Armon C<sup>4</sup>, Brooks JT<sup>1</sup>, Dean B<sup>5</sup><sup>1</sup>Centers for Disease Control and Prevention, Atlanta, GA, USA, <sup>2</sup>International Association of Physicians in AIDS Care, Washington, DC, USA, <sup>3</sup>Northwestern University Feinberg School of Medicine, Chicago, IL, USA, <sup>4</sup>Cerner Corporation, Vienna, VA, USA, <sup>5</sup>Cerner Research, Culver, City, CA, USA

**OBJECTIVES:** Monitoring transmitted drug resistance can inform national treatment recommendations, but U.S. data from patients initiating antiretroviral therapy (ART) are few. **METHODS:** Using data from HIV Outpatient Study (HOPS) participants from 10 U.S. HIV clinics diagnosed with HIV infection in 1999 or later and the International AIDS Society (IAS) December 2010 guidelines, we assessed the frequency of major ART resistance mutations in isolates from patients who underwent genotypic resistance testing (GT) before initiating ART. We used logistic regression to assess factors associated with having undergone GT and with harboring major IAS resistance. **RESULTS:** Among 1,484 eligible patients, 711 (47.9%) had GT before first ART, increasing from 15.2% in 1999-2002 to 71.5% in 2009-2011 ( $p<0.001$ ). During 1999-2011, patients who had GT were more likely to have been men who have sex with men, to have had CD4+ cell count  $>200$  cells/mm<sup>3</sup>, and to have had their first HOPS visit in 2003 or later (all  $p<0.05$ ). Of 695 (97.7%) patients with evaluable GT results, 114 (16.4%) had a major IAS-defined mutation; mutations to nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors and protease inhibitors were present, respectively, in 8.9%, 7.8% and 3.2% of patients. Four (0.6%) patients had triple-class resistance and one patient had resistance to T-20, a drug in a novel fusion inhibitor class. We found no evidence of a temporal increase in the frequency of any major IAS mutation (13.2% in 1999-2002 to 17.5% in 2009-2011,  $p=0.22$ ) or in the frequency of mutations to any of the three main drug classes. **CONCLUSIONS:** During 1999-2011, GT use for ART-naïve patients became more common without evidence of increases in frequency of transmitted HIV resistance in our large heterogeneous HIV cohort.

## PIN12

## EFFECTIVENESS OF THE ROTAVIRUS MONOVALENT VACCINE IN COLOMBIA: PRELIMINARY RESULTS OF A CASE-CONTROL STUDY

Paternina-Caicedo A<sup>1</sup>, Cotes K<sup>2</sup>, Coronell-Rodríguez W<sup>1</sup>, Alvis-Guzmán N<sup>1</sup>, De la Hoz-Restrepo F<sup>2</sup><sup>1</sup>Universidad de Cartagena, Cartagena de Indias, Colombia, <sup>2</sup>Universidad Nacional de Colombia, Bogotá, Colombia

**OBJECTIVES:** To assess the effectiveness of the rotavirus monovalent vaccine in Colombia. **METHODS:** A hospital based case-control study was carried out. Cases were positive rotavirus diarrhea patients admitted to emergency departments in seven health care institutions across the country. Controls were non-rotavirus diarrhea patients admitted to emergency the department in those institutions. Vesikari scale was estimated to assess effectiveness of the vaccine against severe diarrhea. Multivariable analysis was made with logistic regression. A  $p$ -value  $<0.05$  was considered statistically significant. **RESULTS:** A total of 60 cases and 337 controls were used for analysis. Effectiveness of two-dose vaccination was 46.8% (95% Confidence Interval [95%CI], -29.6 to 78.3). Effectiveness of two-dose vaccination applied at recommended age (less than 8 months of age) was 55.8% (95%CI, 7.3 to 78.9). Two-dose vaccination effectiveness in the multivariable analysis was 62.6% (95%CI, 0.30 to 85.9), and if applied at recommended age was 71.9% (95%CI, 35.5 to 87.8). Results showed an effectiveness decline after 9 months of vaccination. Effectiveness was 69% (95%CI, 26.7 to 86.9) during the nine months after vaccination, and 40.5% (95%CI, -31.3 to 73.1) after those nine

months. **CONCLUSIONS:** Rotavirus vaccination with the monovalent vaccine was effective in Colombia, if applied to recommended age.

## PIN13

## LINICAL EFFICACY/EFFECTIVENESS OF COMBINED THERAPY WITH INTERFERON (PEGYLATED OR NON-PEGYLATED) + RIBAVIRIN IN PATIENTS WITH CHRONIC HEPATITIS C

Almadiyeva A, Kostyuk A

National Center for Health Development, Astana, Kazakhstan

**OBJECTIVES:** To assess the clinical effectiveness of combined therapy with interferon (pegylated or non-pegylated) and ribavirin versus interferon alone for the treatment of chronic HCV in adult patients. **METHODS:** We used standard HTA methods as PICO, comparative analysis, descriptive epidemiology to evaluate a clinical effectiveness of the anti HCV treatment in several respectable trials. Studies eligible for inclusion were systematic reviews of randomized controlled trials (RCTs), RCTs, HTA reports, economic evaluations, high quality primary studies (preferably RCTs). Preference was given to references published in the English or Russian languages and preferably published within the past 10 years (2002 forward). **RESULTS:** All subgroups of included trials consisted of 13,331 patients with chronic hepatitis C without HIV infection or liver transplantation with diagnosed on the presence of serum hepatitis C virus RNA plus elevated serum transaminase activity for more than 6 months or chronic hepatitis documented by liver biopsy. All of the included studies detected the clinical efficacy of combined therapy of IFN + RBV. According to trials, patients with non-1 genotype had higher virological response rates than patients with genotype 1. Genotype 1 patients had significantly higher SVR rates when treated for 48 weeks compared with 24 weeks. PEG and four IFN trials reported alanine aminotransferase (ALT) response rates after treatment. Sustained biochemical response was greater for IFN + RBV compared with IFN monotherapy or IFN with placebo, reaching significance in two trials and borderline significance in one trial. **CONCLUSIONS:** The clinical effectiveness of the combined therapy with ribavirin and interferon is convincing. However, using the ribavirin in combination with interferon (pegylated or non-pegylated) can not be final, owing to the many adverse effects. Assessment of the recovery of patients by the sustained virologic response should not be so pragmatic, because it is only a change of the "surrogate" criterias.

## PIN14

## ANTIBIOTICS IN SERBIAN HOME PHARMACIES

Paut Kusturica M<sup>1</sup>, Stojancevic M<sup>2</sup>, Stanimirov B<sup>1</sup>, Pavlovic N<sup>2</sup><sup>1</sup>University of Novi Sad, Faculty of Medicine, Novi Sad, Serbia and Montenegro, <sup>2</sup>Medical Faculty, Novi Sad, Serbia and Montenegro

**OBJECTIVES:** The continuing spread of antimicrobial resistance, due to uncontrolled antibiotic use, is a major public health problem worldwide. The aim of this study is to make an inventory of the antimicrobials for systemic use in the home pharmacies of the urban and rural populations in South Ba ka District, Serbia. **METHODS:** This study was performed in 6 months period (February - July 2010) on a sample of 208 households (108 in urban and 100 in rural communities) in South Ba ka District, Serbia. The families were chosen randomly and the data were collected by checking the inventory of antibiotics in the home pharmacies. **RESULTS:** The total number of drug packages present in 208 households was 2221. Every other household had at least one package belonging to J01 class stored at home (51.0% in rural and 65.8% in urban households). A total number of 89 packages belonging to J01 class were present in the surveyed rural families which constitutes 8.9% of total stored drugs. In urban families, the number of packages of antibiotics was 113 (9.3% of total drugs stored). The average number of antibacterial drug packages per household was 0.9 (range: 0-4) in rural and 1.0 (range: 0-6) in urban families. The most frequent antibacterial agents both in rural and urban households was amoxicillin (20.1%), followed by cefalexin (14.8%) and amoxicillin+clavulanic acid (14.2%). **CONCLUSIONS:** According to this study, antibiotics are widely stocked among both rural and urban communities in South Ba ka District, Serbia, which requires further investigation of this practice.

## PIN15

## USE OF ANTI-INFECTIVES FOR SYSTEMIC ADMINISTRATION IN SERBIA IN 2011

Tomic Z, Sabo A, Milijasevic B, Stilinovic N, Horvat O

Faculty of Medicine, University of Novi Sad, Novi Sad, Serbia and Montenegro

**OBJECTIVES:** The aim of the study was to analyze use of anti-infective drugs for systemic administration (ATC-group J) in Serbia in 2011 year. **METHODS:** Data about use of anti-infective drugs for systemic administration in Serbia in 2011 was taken from the Agency for Drugs and Medical Devices of Serbia. **RESULTS:** Use of all drugs in Serbia in 2011 was 1,104.57 DDD/1000 inhabitants/day. ATC-group J was on the seventh place according to amount of DDDs with 27.35 DDD/1000 inh/day or 2.48% of total consumption. According to the funding spend, this group was on the second position with 77,800,748.63€. In this group, subgroup with highest consumption were antibacterial drugs for systemic use (subgroup J01), with 26.68 DDD/1000 inh/day or 97.55% of total use in group J. This subgroup takes first place in funding spent with 52,801,780.13€ or 67.87% of total expended finances in this group in 2011. Beta-lactam antibacterial drugs with 14.98 DDD/1000 inh/day or 56.15% were drugs with highest use in this subgroup, macrolides and lincosamides were at second place with 5.11 DDD/1000 inh/day or 19.15%, while on the third place were quinolones with 2.66 DDD/1000 inh/day or 9.97% of total drug utilization inside this subgroup. Funding spent on beta-lactam antibacterial drugs was 29,522,197.18€ or 55.91%, macrolides and lincosamides 10,811,308.09€ or 20.48%, and for quinolones 6,286,373.19€ or 11.91% of total funding spent for subgroup J01 in 2011 year. **CONCLUSIONS:** In comparison to 2010 spending of group J in Serbia in 2011 year was increased for